

## REMARKS

The Examiner states that Claims 1-10 are pending in the Application; Claims 2-6 have been withdrawn from consideration; and Claims 1, 8 and 10 are rejected. The Examiner, however, has provided no rationale why claims 2-6 have been withdrawn from consideration. Clarification is respectfully requested.

The Examiner rejected claims 1, 8 and 10 under 35 USC 103 as being unpatentable over Fabo (WO -076) in view of Canadian Application 2,101,509. The Examiner relies on Fabo to describe:

...essentially the entire claimed genus of articles and accompanying methods for adhering a prosthesis to a human or animal body which imply only clearly conventional method steps, the reference lacking only a teaching that the elements being bonded together are a prosthesis to a human or animal body. However, the secondary reference discloses (note particularly page 4, lines 6-13, page 5 lines 1-5, lines 11-12 and particularly lines 17-20 and claim 1) the missing element that prosthesis materials may be attached to the human body such as the chest wall by suitable silicone type adhesives (e.g., page 5, lines 17-19)...

Applicant respectfully requests reconsideration and early allowance of the claims. Applicants' invention relates to a novel method for adhering a prosthesis to a human or animal body with an adhesive device (and the prosthesis with the adhesive device adhered thereto). The improvement in the present process is the use of an adhesive device comprising a carrier sheet, said carrier sheet having at least two surfaces. On one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m<sup>2</sup>, said gel having sufficient tack to adhere to the prosthesis. On a second surface of the carrier sheet is a second

continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m<sup>2</sup>, said gel having sufficient tack to adhere to the human or animal body.

Fabo, on the other hand, does not teach this method (or composition). Specifically, nothing in the reference teaches, suggests, anticipates or renders obvious a method of using a silicone gel composition to adhere a prosthesis to a human or animal body. Rather, Fabo teaches that the compositions disclosed therein were useful in the healthcare industry as dressings.

As set forth by the Examiner, the Board of Appeals did reject the original claims in this case over Fabo. In these original claims, however, the prosthesis and human or animal body were claimed as “substrates”. As such, the rationale behind the Board’s decision was that top sheet 4 and protective layer 5 in the Fabo reference were “substrates” which were adhered together with the gel. The present claims which have been limited to prosthesis and human or animal body were presented in response to the Board decision. It is now clear that nothing in this reference describes the “accompanying methods” of the present invention – i.e., adhering a prosthesis to a human or animal body with the gel adhesive.

The Canadian Patent Application teaches a breast enhancement device. Essentially, the device is adhered to the chest wall of the wearer with an adhesive. As taught on page 5 of the application, the adhesive may be silicone medical adhesive Type A sold by Dow Corning Corporation. As such, the Examiner contends that the breast prosthesis is adhered to a human body as claimed in the present invention.

As detailed in the attached literature, however, the type of adhesive taught in the reference is not a gel. Rather, it is a structural adhesive or sealant (cement and glue). It is sticky (like honey) before cure, but it forms a strong rubber with a tack free surface after cure. The cure

is initiated and completed when the adhesive is in contact with the substrate. It is chemically bonded to the adhered surface, and usually cannot be removed without damaging the substrate.

The adhesive gels claimed in the present application, on the other hand, have pressure sensitive adhesive behavior. Specifically, the gel adhesive-substrate interface does not resist separation when the adhesive is peeled off. Rather, because the gel has the properties of excellent wetting, spreadability and visco-elasticity they are able to stick quickly to the surface and develop physical interactions (NOT chemical as in structural adhesives). As such, they can be removed without deteriorating the surface and leaving residues.


Because of these differences, the gel is a much more 'comfortable adhesive'. Picture, for example, the difference between a soft, movable gel against the skin and a rubber cement. Moreover, because of these properties and the fact that the gel retains its tack after removal, the adhesive can be easily removed, moved and reused. In addition, these properties allow for quick, easy and comfortable repositioning of medical prosthesis.

Since nothing in either of the references teaches or discloses the use of gel adhesives as a method for adhering prosthesis, Applicant contends that the references do not render the present invention obvious as required under 35 USC 103(a). Applicants, therefore, respectfully request the Examiner reconsider the rejection and allow the claims to issue.

The present response is being submitted within four months of the Office Action. As such, Applicant hereby requests a one month extension of time. In addition, Applicant hereby petitions for any other necessary extensions of time. You are authorized to charge deposit account 04-1520 for any fees necessary to maintain the pendency of this application.

Respectfully Submitted,

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